IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Adam S. Cantor et al.	Art Unit	: 1615
Serial No.	: 09/965,610	Examiner	: Isis A. D. Ghali
Filed	: September 26, 2001	Conf. No.	: 8132
Title	: COMPOSITION FOR TRANSDERMAL DELIVERY OF FENTANYL		

Mail Stop Pre-Appeal Brief - Patents
Commissioner for Patents
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PRE-APPEAL BRIEF

Status of Claims

Claims 1-9, 16-18, 28-29, 35-36, and 39-103 are pending. Claims 48-51 and 55-91 have been withdrawn. Claims 1-5, 35, 39-42, 52-53, and 91-97 stand rejected under 35 USC § 102(b) over Miranda et al., US 5,474,783. Claims 1-9, 16-18, 28-29, 35-36, 39-47, 52-54, and 92-103 stand rejected under 35 USC § 103 over Miranda in view of Garbe et al., WO 96/08229.

Argument

The claims are directed towards transdermal drug delivery compositions for delivering fentanyl "consisting essentially of" an acrylate copolymer, fentanyl, and, in some cases, certain specified ingredients (adjuvants, plasticizers, and tackifiers). The claims stand rejected as anticipated by Miranda, or obvious in view of Miranda plus Garbe. Miranda describes transdermal drug delivery compositions that **require** at least two polymers having different solubility parameters. In one embodiment, one of the polymers is a polyacrylate adhesive and the other is a polysiloxane adhesive. Miranda criticizes compositions that include only a single adhesive polymer (e.g., col. 2, lines 4-16), and states that the second adhesive polymer modulates the release of the drug from the adhesive composition (col. 6, lines 16-19 and col. 8, lines 30-43) (emphasis added):

> The invention is **premised** on the discovery that the transdermal permeation rate of a drug from the multiple adhesive system can be selectively modulated by adjusting the solubility of the drug in the device .... In a particularly preferred embodiment of the invention, the multiple polymer adhesive comprises a blend of an acrylic pressure-sensitive adhesive and a silicone

> pressure-sensitive adhesive .... **The amount of acrylic-based polymer (hereinafter referred to broadly as a polyacrylate) and silicone-based polymer (hereinafter referred to broadly as a polysiloxane) is selected to modify the saturation concentration of the drug in the multiple polymer adhesive system in order to affect the rate of delivery of the drug from the system and through the skin.**

Miranda, therefore, clearly teaches adding an amount of polysiloxane to the polyacrylate that is specifically designed to affect the transdermal drug delivery properties of the composition.

As the Examiner correctly notes on pp. 10-11 of the Office Action mailed 3/25/10, "'consisting essentially of' limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition." In this case, the listed ingredients are an acrylate copolymer, fentanyl, and, in some cases, certain specified ingredients (adjuvants, plasticizers, and tackifiers). The "basic and novel characteristics" of this composition relate to the transdermal delivery of fentanyl. Accordingly, the issue with respect to Miranda is whether the "consisting essentially of" language in the claims excludes Miranda's polysiloxanes. Resolution of this issue turns on whether inclusion of Miranda's polysiloxanes would affect the transdermal drug delivery properties of the claimed compositions. An ingredient may "affect" the transdermal drug delivery properties of the composition either positively or negatively. The "consisting essentially of" language does not merely exclude ingredients that detrimentally affect the transdermal drug delivery properties of the composition.

The Examiner's position is that the "consisting essentially of" language in Applicants' claims does not exclude Miranda's polysiloxanes, presumably because there is no evidence that inclusion of the polysiloxanes detrimentally affects the properties of the claimed transdermal drug delivery compositions. The Examiner states (p. 11):

> [A]pplicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition .... Applicants disclosed in their specification, page 7, lines 20-25, that polysiloxanes are suitable pressure sensitive adhesive for their invention. Nothing of record shows that polysiloxanes have detrimental effect on the acrylate polymer of the invention.

Miranda itself belies the Examiner's position. The entire reason Miranda includes the polysiloxanes is to affect the drug delivery characteristics of the composition. As is evident from

the passage quoted above, Miranda specifically instructs selecting the amount of polysiloxane to achieve this very purpose. It is irrelevant that there is no evidence of record showing that Miranda's polysiloxanes would have a detrimental effect on Applicants' acrylate copolymer. "Detrimental effect" is not the standard. It is equally irrelevant that Applicants' specification discloses polysiloxanes because merely listing them says nothing about whether they affect the transdermal drug delivery characteristics of an acrylate-containing composition. The only evidence of record on the issue of whether Miranda's polysiloxanes would affect the drug delivery properties of an acrylate-containing transdermal drug delivery composition is what Miranda says—and Miranda makes absolutely clear that the polysiloxanes, when added in the amounts Miranda instructs, do, in fact, affect the transdermal drug delivery properties of the composition. The Examiner has produced no evidence to the contrary. The "consisting essentially of " language included in each of Applicants' claims, therefore, plainly excludes Miranda's polysiloxanes because, based upon what Miranda itself discloses, the additional presence of such polysiloxanes would affect the drug delivery characteristics of Applicants' acrylate copolymer-based, transdermal drug delivery compositions. Accordingly, Miranda cannot anticipate the claims.

The Examiner's proposed combination of Miranda and Garbe for obviousness purposes is equally improper. The rejection is based upon the premise that because Garbe describes acrylate polymers without polysiloxanes, it would have been obvious to combine the teachings of the two references, while at the same time omitting Miranda's polysiloxanes (p.11):

> Garbe teaches that acrylates can be used without polysiloxanes adhesives. The copolymer instantly claimed was known in the art at the time of the invention. Further, it has been held that omission of an element and its function is obvious if the function of the element is not desired.

The Examiner's proposed combination ignores the fact that Miranda expressly teaches that the presence of the polysiloxane is critical. In fact, in Miranda's own words, Miranda's invention is "premised" on including more than one polymer in the drug delivery composition for the purpose of affecting transdermal drug delivery. In Miranda's compositions, the function of the polysiloxane is absolutely desired and necessary. In this regard, it is irrelevant that Garbe's compositions lack the polysiloxane because one cannot use the absence of polysiloxanes

in Garbe's composition as a license to ignore Miranda's plain admonition that a transdermal drug delivery-altering amount of polysiloxane must be included. On the contrary, what it means is that the two references simply cannot be combined—or, at the very least, cannot be combined to yield a composition that lacks Miranda's polysiloxanes, which Applicants' claims exclude. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448, 230 USPQ 416, 419 (Fed. Cir. 1986), quoting *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965):

> It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

For at least the reasons discussed above, the pending claims are patentable over Miranda, alone or in combination with Garbe. Accordingly, Applicants respectfully request the Examiner to withdraw the rejections and allow the claims. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:/May 10, 2010/_____

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